



## Patient Information Sheet

### Paroxetine hydrochloride (marketed as Paxil)

This is a summary of the most important information about paroxetine. For details, talk to your healthcare professional.

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#### FDA ALERT [05/2005] – Suicidal Thoughts or Actions in Children

**Patients with depression or other mental illnesses often think about or attempt suicide. Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior should be evaluated by their healthcare professional right away.**

**Although paroxetine is prescribed for children, it has not been approved by FDA for use in children.**

*This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.*

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#### What Is Paroxetine?

Paroxetine is in a class of medicines called selective serotonin reuptake inhibitors (SSRIs).

Paroxetine tablets and oral suspension are used to treat:

- Depression
- Panic disorder
- Social anxiety disorder (SAD)
- Obsessive-compulsive disorder (OCD)
- Posttraumatic stress disorder (PTSD)
- Generalized anxiety disorder (GAD)

Paroxetine CR is used to treat:

- Depression
- Panic disorder
- Social anxiety disorder (SAD)
- Premenstrual dysphoric disorder (PMDD)

#### Who Should Not Take Paroxetine?

- **Never take paroxetine if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking paroxetine close in time to an MAOI can result in serious, sometimes fatal, reactions, including:**
  - High body temperature
  - Coma
  - Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

- **Never take paroxetine if you are taking Mellaril (thioridazine),** used to treat schizophrenia, because it can result in serious heart beat problems.

#### What Are The Risks?

- **Suicidal thoughts or actions:** See FDA Alert.
- **Stopping paroxetine:** Do not stop taking paroxetine suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Bleeding problems:** Paroxetine may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen), or other drugs that affect bleeding.
- **Mania:** You may become hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion) even if you are not taking paroxetine close in time with a MAOI.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking paroxetine late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include weakness, dry mouth, constipation, yawning, infection, diarrhea, sweating, dizziness, tremor, nervousness, nausea, difficulty sleeping, decreased appetite, and sleepiness.
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver or kidney disease, or glaucoma. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

#### Are There Any Interactions With Drugs or Foods?

- Paroxetine may interact with medicines other than the ones already mentioned in this information sheet. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take.
- If you plan to drink alcohol, talk to your healthcare professional.

#### How Do I Take Paroxetine?

- Paroxetine is taken by mouth, with or without food, once a day.
- Swallow paroxetine tablets whole. Do not crush or chew them.

#### Is There Anything Else I Need to Know?

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

**Paxil FDA Approved 1992  
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